



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,052	08/28/2001	Arthur B. Raitano	511582002800	6518

36327 7590 06/20/2005

AGENSYS C/O MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE, SUITE 500
SAN DIEGO, CA 92130

EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,052

Applicant(s)

RAITANO ET AL.

Examiner

David J. Blanchard

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibits A & B

18

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 March 2005 has been entered.
2. Claims 88-98 are pending and under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

4. The objection to the specification for containing embedded hyperlinks is withdrawn in view of then amendments to the specification.
5. The objection to the specification for containing typos in the titles in the titles in Examples 13, 36 and 37 is withdrawn in view of the amendments to the specification.
6. The rejection of claims 88-98 under 35 U.S.C. 101 as being drawn to non-statutory subject matter is withdrawn in view of the amendment to claim 88, i.e., the insertion of the term "isolated".
7. The rejection of claims 88-98 under 35 U.S.C. 103(a) as being unpatentable over Williams et al in view of Campbell A. M. and Queen et al and Reiter et al is withdrawn in

Art Unit: 1642

view of applicant's arguments and also in view of the fact that Williams does not teach the expression of the OIP5 protein (identical to SEQ ID NO:728 of the instant claims) and acknowledges that the function of the OIP5 protein is unknown (see page 174, right column).

Response to Arguments

8. The rejection of claims 88-98 under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility is maintained.

The response filed 3/17/2005 has been carefully considered, but is deemed not to be persuasive. The response states that as shown in the specification, mRNA encoding the claimed protein was expressed in cancer tissues and was only expressed in normal testis tissue (Example 4) and because the protein is differentially expressed, applicant asserts that antibodies directed to a protein having at least 90% homology to SEQ ID NO:728 have utility as a cancer diagnostic and therapeutic agent. In response to this argument, no evidence has been submitted that it is the norm rather than the exception that protein levels are increased when gene amplification occurs in cancer. Indeed, given the disclosures in the art, such as Pennica et al, Konopka et al, Haynes et al, Lewin B. and Gokman-Polar et al that there is not always such a correlation, the skilled artisan would not assume it is so, but would perform the experiment to verify it. This further experimentation is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The data set forth in the

Art Unit: 1642

specification is preliminary at best. The literature (noted above) evidences that gene amplification does not reasonably correlate with increased mRNA or polypeptide expression. Therefore, further research would be required by the skilled artisan to determine if the disclosed results regarding mRNA expression in cancer tissues is reflected at the polypeptide level. Since the asserted utility that the claimed polypeptides can be used as a cancer diagnostic is not in currently available form, the asserted utility is not substantial. As the courts have discussed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup Ct 1966), an asserted utility must exist in currently available form.

For these reasons, the rejection is maintained.

9. The rejection of claims 88-98 under 35 U.S.C. 112, first paragraph, since the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention is maintained.

10. The rejection of claims 88-98 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention is maintained.

The response filed 3/17/2005 did not address this rejection and thus, the rejection is maintained for reasons already of record.

Art Unit: 1642

11. The rejection of claims 88-98 under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims is maintained.

The response filed 3/17/2005 did not address this rejection and thus, the rejection is maintained for reasons already of record.

12. The rejection of claims 88-95 and 97-98 under 35 U.S.C. 102(e) as being anticipated by Tang et al (WO 01/53312, 102(e) date 1/21/2000, lds filed 2/11/2003) is maintained.

Applicant is reminded that because the claimed subject matter does not have a specific and substantial asserted utility or a well established utility, the priority date of the claims are granted the filing date of the instant application, i.e., 8/28/01, for purposes of applying prior art.

The response filed 3/17/2005 has been carefully considered, but is deemed not to be persuasive. The response argues that the applied Tang et al reference was published 26 July 2001 and acknowledges that the reference does claim priority to applications filed before the earliest priority claimed by the present application, specifically, August 28, 2000. In response to this argument and as discussed above the instant application is granted the filing date of 8/28/2001 because the claimed subject matter is not supported by a specific and substantial asserted utility or a well established utility. Further, the applied reference of Tang et al was filed after

Art Unit: 1642

11/29/2000, published in English and designated the US and thus, is available under 102(e) as of the filing date or an earlier filing date for which benefit is sought.

Accordingly, as applied in the rejection the 102(e) date of the Tang reference is 1/21/2000, the filing date of USSN 09/488,725, which discloses SEQ ID Nos:3368 and 6940 and antibodies that bind these polypeptides as applied in the previous Office Action (see Exhibits A and B attached to the back of this Office Action as evidence for SEQ ID Nos:3368 and 6940 in USSN 09/488,725).

Applicant also submits a declaration under 37 CFR 1.131 which avers that applicants were in possession of the claimed sequence before the filing date of the 09/598,042 application, filed 6/9/2000. The Declaration filed on 3/17/2005 under 37 CFR 1.131 has been considered, but is ineffective to overcome the applied reference because the date of the applied reference is that of USSN 09/488,725, filed 1/21/2000 as discussed above. Further, the claimed invention is not actually reduced to practice unless there is a known utility (MPEP 2138.05).

Even if the claimed invention had utility, the evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the applied reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). A general allegation that the invention was completed prior to the date of the reference is not sufficient. Ex parte

Art Unit: 1642

Saunders, 1883 C.D. 23, 23 O.G. 1224 (Comm'r Pat. 1883). Similarly, a declaration by the inventor to the effect that his or her invention was conceived or reduced to practice prior to the reference date, without a statement of facts demonstrating the correctness of this conclusion, is insufficient to satisfy 37 CFR 1.131. 37 CFR 1.131(b) requires that original exhibits of drawings or records, or photocopies thereof, accompany and form part of the affidavit or declaration or their absence satisfactorily explained. In *Ex parte Donovan*, 1890 C.D. 109, 52 O.G. 309 (Comm'r Pat. 1890) the court stated

If the applicant made sketches he should so state, and produce and describe them; if the sketches were made and lost, and their contents remembered, they should be reproduced and furnished in place of the originals. The same course should be pursued if the disclosure was by means of models. If neither sketches nor models are relied upon, but it is claimed that verbal disclosures, sufficiently clear to indicate definite conception of the invention, were made the witness should state as nearly as possible the language used in imparting knowledge of the invention to others. See MPEP 715.07 and 2138.04.

In addition, the factual evidence provided in the declaration is not sufficient to show diligence because the facts provided in the declaration do not account for the entire time period during which diligence is required, which begins just prior to the effective date of the reference (Tang et al, 1/21/2000) and ends with the date of a reduction to practice, either actual or constructive. An applicant must account for the entire period during which diligence is required. *Gould v. Schawlow*, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (Merely stating that there were no weeks or months that the invention was not worked on is not enough.); *In re Harry*, 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964) (statement that the subject matter "was diligently reduced to practice" is not a showing but a mere pleading). A 2-day period lacking

activity has been held to be fatal. *In re Mulder*, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983). See MPEP 715 and 2138.06.

For these reasons the rejection is maintained.

13. The rejection of claims 88-98 under 35 U.S.C. 103(a) as being unpatentable over Tang et al (WO 01/53312, 102(e) date 1/21/2000, Ids filed 2/11/2003) in view of Reiter et al (US Patent 6,261,791 B1, 5/25/1999) is maintained.

The response filed 3/17/2005 has been carefully considered, but is deemed not to be persuasive. The response states that as discussed above for Tang et al, the Tang et al reference is not available as prior art against the present claims. In response to this argument, the arguments above for Tang et al apply here as well and thus, Tang is available as prior art against the present claims. The response also argues that the Office has not articulated a prima facie case of obviousness and the rejection should be withdrawn. Applicant's response does not provide any reasoning why one of ordinary skill in the art would not be motivated to combine the references, however, for completeness of the record the following is reiterated for applicant's convenience. The examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CPA 1975). In this case, the explicit teachings of Tang et al suggest the combination in that Tang et al teach immunoconjugates comprising a cytotoxic agent conjugated to antibodies that bind the polypeptides of SEQ ID Nos:3368 and 6940 (identical to the

Art Unit: 1642

claimed polypeptide sequence of SEQ ID NO:728) and it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have conjugated the specific cytotoxic agents taught by Reiter et al to the antibodies taught by Tang et al in view of the teachings of Tang, which suggest conjugation to a cytotoxic agent.

For these reasons the rejection is maintained.

Conclusion

14. No claim is allowed.

15. This is a RCE of applicant's earlier Application No. 09/942,052. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1642

the advisory action. In no ~~event~~^{case} will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

6/2/09

RESULT 1
 US-09-488-725A-3368
 ; Sequence 3368, Application US/09488725A
 ; GENERAL INFORMATION:
 ; APPLICANT: Hyseq Inc
 ; TITLE OF INVENTION: Novel Nucleic Acid and Polypeptides
 ; FILE REFERENCE: 784FLPCT
 ; CURRENT APPLICATION NUMBER: US/09/488,725A
 ; CURRENT FILING DATE: 2000-12-22
 ; PRIOR APPLICATION NUMBER: US/09/488,725
 ; PRIOR FILING DATE: 2000-01-21
 ; PRIOR APPLICATION NUMBER: US09/552,317
 ; PRIOR FILING DATE: 2000-04-25
 ; PRIOR APPLICATION NUMBER: US09/598,042
 ; PRIOR FILING DATE: 2000-06-20
 ; PRIOR APPLICATION NUMBER: US09/620,312
 ; PRIOR FILING DATE: 2000-07-19
 ; PRIOR APPLICATION NUMBER: US09/653,450
 ; PRIOR FILING DATE: 2000-08-31
 ; PRIOR APPLICATION NUMBER: US09/662,191
 ; PRIOR FILING DATE: 2000-09-14
 ; PRIOR APPLICATION NUMBER: US09/693,036
 ; PRIOR FILING DATE: 2000-10-19
 ; PRIOR APPLICATION NUMBER: US09/727,344
 ; PRIOR FILING DATE: 2000-11-29
 ; NUMBER OF SEQ ID NOS: 7144
 ; SOFTWARE: pt_FL_genes_b Versions 1.0
 ; SEQ ID NO 3368
 ; LENGTH: 230
 ; TYPE: PRT
 ; ORGANISM: Homo sapiens
 US-09-488-725A-3368

Exhibit A

Query Match 100.0%; Score 1198; DB 18; Length 229;
 Best Local Similarity 100.0%; Pred. No. 1.7e-116;
 Matches 229; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	1	MAAQPLRHRSRCATPPRGDFCGGTERAIDQASFTTSMEWDTQVVKGSSPLGPAGLGAEPP	60
Db	1	MAAQPLRHRSRCATPPRGDFCGGTERAIDQASFTTSMEWDTQVVKGSSPLGPAGLGAEPP	60
Qy	61	AAGPOLPSWLQPERCAVFOCAQCHAVLADSVHLAWDLRSILGAVVFSRVTNVNVLEAPFL	120
Db	61	AAGPOLPSWLQPERCAVFOCAQCHAVLADSVHLAWDLRSILGAVVFSRVTNVNVLEAPFL	120
Qy	121	VGIEGSLKGSTYNLLFCGSCGIPVGFHLYSTHAALALRGHFLSSDKMVCYLLKTKAIV	180
Db	121	VGIEGSLKGSTYNLLFCGSCGIPVGFHLYSTHAALALRGHFLSSDKMVCYLLKTKAIV	180
Qy	181	NASEMDIQNVPLSEKIAELKEKIVLTHNRLKSLMKILSEVTPDQSKPEN	229
Db	181	NASEMDIQNVPLSEKIAELKEKIVLTHNRLKSLMKILSEVTPDQSKPEN	229

RESULT 13
 US-09-488-725A-6940
 ; Sequence 6940, Application US/09488725A
 ; GENERAL INFORMATION:
 ; APPLICANT: Hyseq Inc
 ; TITLE OF INVENTION: Novel Nucleic Acid and Polypeptides
 ; FILE REFERENCE: 784FLPCT
 ; CURRENT APPLICATION NUMBER: US/09/488,725A
 ; CURRENT FILING DATE: 2000-12-22
 ; PRIOR APPLICATION NUMBER: US/09/488,725
 ; PRIOR FILING DATE: 2000-01-21
 ; PRIOR APPLICATION NUMBER: US09/552,317
 ; PRIOR FILING DATE: 2000-04-25
 ; PRIOR APPLICATION NUMBER: US09/598,042
 ; PRIOR FILING DATE: 2000-06-20
 ; PRIOR APPLICATION NUMBER: US09/620,312
 ; PRIOR FILING DATE: 2000-07-19
 ; PRIOR APPLICATION NUMBER: US09/653,450
 ; PRIOR FILING DATE: 2000-08-31
 ; PRIOR APPLICATION NUMBER: US09/662,191
 ; PRIOR FILING DATE: 2000-09-14
 ; PRIOR APPLICATION NUMBER: US09/693,036
 ; PRIOR FILING DATE: 2000-10-19
 ; PRIOR APPLICATION NUMBER: US09/727,344
 ; PRIOR FILING DATE: 2000-11-29
 ; NUMBER OF SEQ ID NOS: 7144
 ; SOFTWARE: pt_FL_genes_b Versions 1.0
 ; SEQ ID NO 6940
 ; LENGTH: 231
 ; TYPE: PRT
 ; ORGANISM: Homo sapiens
 US-09-488-725A-6940

Exhibit B

Query Match 100.0%; Score 1198; DB 18; Length 231;
 Best Local Similarity 100.0%; Pred. No. 1.7e-116;
 Matches 229; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy	1	MAAQPLRHRRCATPPRGDFCGGTERAIDQASFTTSM EWDTQVVKGSSPLGPAGLGAEEP	60
Db	3	MAAQPLRHRRCATPPRGDFCGGTERAIDQASFTTSM EWDTQVVKGSSPLGPAGLGAEEP	62
Qy	61	AAGPQLPSWLQPERCAVFQCAQCHAVLADSVHLAWDLSRSLGAVVFSRVTNVNVLEAPFL	120
Db	63	AAGPQLPSWLQPERCAVFQCAQCHAVLADSVHLAWDLSRSLGAVVFSRVTNVNVLEAPFL	122
Qy	121	VGIEGSLKGSTYNLLFCGSCGIPVGFHLYSTHAALALRGHFCLSSDKMVCYLLKTKAIV	180
Db	123	VGIEGSLKGSTYNLLFCGSCGIPVGFHLYSTHAALALRGHFCLSSDKMVCYLLKTKAIV	182
Qy	181	NASEMDIQNVPLSEKIAELKEKIVLTHNRLKSLMKILSEVTPDQSKPEN	229
Db	183	NASEMDIQNVPLSEKIAELKEKIVLTHNRLKSLMKILSEVTPDQSKPEN	231